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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,975	08/26/2003	Dusan Miljkovic	100700.0016US1	4147

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
03/25/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/648,975	MILJKOVIC, DUSAN	
	Examiner	Art Unit	
	FRANK CHOI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/5/2010 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miljkovic (US Pat. 5,962,049) in view of Naghii et al. (Abstract), Nielsen, Volpe et al. (Abstract) and FDA Talk Paper (9/23/1997).

The claimed invention is directed to a kit containing a dietary supplement containing a carbohydrate-boron complex having a boron-ligand association constant of at least 2,500 and at least one calcium, magnesium and vitamin D, and instructions and a method of increasing steroid concentration in a human by administering a carbohydrate-boron complex having a boron-ligand association constant of at least 2,500, measuring increase in steroid concentration and providing instructions.

Miljkovic discloses a nutritional supplement containing a carbohydrate-boron complex which is charged neutralized with calcium or magnesium, where the carbohydrate ligand can be

fructose or have a boron-ligand association constant is at least 5000 where the ligand is mannose, mannitol, sorbose or sorbitol (Claims 4-6, 11,12). It is disclosed that Beta-fructofuranose has a boron association constant of 6,000 (Column 3, lines 60-68, Column 4, lines 1-38). It is disclosed that boron offers significant benefits with respect to bone and joint health and that the optimum daily of intake is about 2-3 mg/day (Column 1, lines 23,24,35,36). It is disclosed that the sugar-boron compounds can be included in pharmaceutical preparations, including with suitable excipients, binders, carriers and other compounds as known in the pharmaceutical arts, including vitamin pills and other forms of supplements, with the dosage providing about 0.01 mg/day/dose to about 10 mg/day/dose or more of boron (Column 5, lines 13-22, Column 6, lines 1-5).

Naghii et al. disclose that supplementation of 10 mg of boron per day for 4 weeks significantly increased plasma estradiol concentrations and there was a trend for plasma testosterone levels to be increased (Abstract).

Neilsen disclose an experiment in which patients were fed a boron-low diet for 63 days and then supplemented with 3 mg/day boron for 49 days and that when compared serum 25 hydroxycholecalciferol was lower in the depletion period compared to the repletion period (Page 59). It is disclosed that the reason for estrogen therapy is to prevent calcium and bone loss which can lead to osteoporosis (page 62).

Volpe et al. disclose that the role of boron in bone metabolism and increasing bone density is most likely to be associated with interactions with other minerals and vitamins, such as calcium, magnesium and vitamin D (Abstract).

The FDA Talk Paper (9/23/1997) discloses that products containing ingredients such as vitamins and minerals are required to have labels identifying them as dietary supplements, providing appropriate serving size information on 14 nutrients, when present at significant levels, including calcium, other vitamins and minerals if they are added or part of a nutritional claim on the label and dietary ingredients for which no Reference Daily Intakes have been established (Pg. 1 of 2).

Miljkovic discloses a carbohydrate-boron complex having a ligand affinity of greater than 2500, including a calcium or magnesium (fructose, mannose, mannitol, sorbose, or sorbitol) boron complex and that boron is important in bone and joint health. The difference between the Miljkovic and the claimed invention is that Miljkovic does not expressly disclose combining with Vitamin D, formulation as a tablet or capsule, a method of increasing steroid concentration in a human with the carbohydrate-boron complex or including instructions. However, the prior art amply suggests the same as Naghii et al. disclose that supplementation of 10 mg of boron per day for 4 weeks significantly increased plasma estradiol concentrations and there was a trend for plasma testosterone levels to be increased; Neilsen disclose an experiment in which patients were fed a boron-low diet for 63 days and then supplemented with 3 mg/day boron for 49 days and that when compared serum 25 hydroxycholecalciferol was lower in the depletion period compared to the repletion period and that that the reason for estrogen therapy is to prevent calcium and bone loss which can lead to osteoporosis; Volpe et al. disclose that the role of boron in bone metabolism and increasing bone density is most likely to be associated with interactions with other minerals and vitamins, such as calcium, magnesium and vitamin D; and The FDA Talk Paper (9/23/1997) discloses that products containing ingredients such as vitamins and

minerals are required to have labels identifying them as dietary supplements, providing appropriate serving size information on 14 nutrients, when present at significant levels, including calcium, other vitamins and minerals if they are added or part of a nutritional claim on the label and dietary ingredients for which no Reference Daily Intakes have been established.

As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the carbohydrate-boron complex would be effective in increasing steroid concentration in humans as boron is disclosed to increase estradiol and testosterone concentration, that increasing serum estradiol would increase bone density, that boron's effect on bone metabolism would be facilitated by the addition of calcium, magnesium and vitamin D, that the dietary supplement can be in any form desired, including pills and mixtures with suitable excipients, binders and carriers and other compounds included as known in the pharmaceutical arts and that the dietary supplement would include instructions so that one would know how to use the dietary supplement and would know the nutritional benefits of taking the dietary supplement, including increasing steroid concentrations of estradiol and testosterone.

The Examiner has duly considered the Applicant's arguments but deems them unpersuasive.

The Supreme Court in KSR International Co. v. Teleflex Inc., held the following:

(1) the obviousness analysis need not seek out precise teachings directed to the subject matter of the challenged claim and can take into account the inferences and creative steps that one of ordinary skill in the art would employ;

(2) the obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents;

(3) it is error to look only the problem the patentee was trying to solve-any need or problem known in the filed of endeavor at the time of invention and addressed by the prior art can provide a reason for combining the elements in the manner claimed;

(4) it is error to assume that one of ordinary skill in the art in attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem-common sense teaches that familiar items may have obvious uses beyond their primary purposes, and in many cases one of ordinary skill in the art will be able to fit the teachings of multiple patents together like pieces of a puzzle (one of ordinary skill in the art is not automaton);

(5) it is error to assume that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try". KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385, 1396, 1397 (U.S. 2007).

The Applicant argues that a person of ordinary skill in the art would be disincentivized to use complexes in which boron is very tightly bound as one would not expect boron to be bioavailable. The Applicant provides no evidence which supports this assertion. As indicated above, the claimed boron complexes are used as dietary supplements which improve bone and joint health. As such, the boron contained in the complexes is bioavailable. The Applicant's evidence only shows that calcium fructoborate is more bioavailable than boron citrate. The Applicant's evidence does not show that one of ordinary skill in the art would consider that carbohydrate –born complexes with a boron-ligand association constant of at least 2,500 to not

be bioavailable. The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). Further, the evidence provided is not in affidavit or declaration form. "The reason for requiring evidence in declaration or affidavit form is to obtain the assurances that any statements or representations made are correct, as provided by 35 U.S.C. 25 and 18 U.S.C. 1001." Permitting a publication to substitute for expert testimony would circumvent the guarantees built into the statute. Ex parte Gray, 10 USPQ2d 1922, 1928 (Bd. Pat. App. & Inter. 1989). As such, the Applicant's unsupported assertion does not overcome the rejection herein.

Contrary to the Applicant's arguments the Examiner has provided the reasoning for modify and/or combining the art, as indicated above. The Applicant cites to Environ Health Perspect. 2002 Oct; 110 Suppl 5, 887-90 and Environ Health Perspect. 1998 Dec. 106 Suppl 6:1585-7 in support of its assertion that one of ordinary skill in the art would not expect the carbohydrate boron complexes to be effective in increase steroid concentrations in the body as chelation therapy is a well known aspect of high-Ka complexes that reduce the bioavailability of the bound metal. As indicated above, the purported evidence is not in affidavit or declaration form. Further, the applicant has not provided a copy of the said references. There is no indication that the cited references disclose that carbohydrate complexes of boron inhibit bioavailability. In any case, Miljkovic clearly suggest, as indicated above, that the claimed carbohydrate boron complexes are bioavailable. As such, the Applicant's unsupported assertion

that one or ordinary skill in the art would not expect the carbohydrate boron complexes to be effective in increasing steroid concentrations in the body does not overcome the rejection herein.

The Applicant's argument that the Examiner is asserting inherency is without merit. Miljkovic discloses that boron offers significant benefits with respect to bone and joint health and that the optimum daily of intake is about 2-3 mg/day. The Applicant has not provided sufficient evidence that refutes that the carbohydrate complexes of boron would not improve bone and joint health.

None of the Applicant's claims set for any specific dosage amount or range with respect to the daily amount or dose. The fact that the method claims now claim that the carbohydrate boron complex increases steroid concentrations does not change this fact. As indicated above, Naghii et al. disclose that supplementation of 10 mg of boron per day for 4 weeks significantly increased plasma estradiol concentrations and there was a trend for plasma testosterone levels to be increased. As such, one of ordinary skill in the art would expect that the carbohydrate boron complexes would also increase plasma estradiol and testosterone.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. The Examiner maintains a flexible schedule, however, the Examiner may generally be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
March 22, 2011

/John Pak/
Primary Examiner, Art Unit 1616